PATENT
Attorney Docket No.: 016285-003710US
Client Ref. No.: 02/MED/122

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 8146
Yuk-Ming Dennis Lo et al.	Examiner: MYERS, Carla J.
Application No.: 10/759,783	Technology Center/Art Unit: 1634
Filed: January 16, 2004	RESPONSE TO RESTRICTION REQUIREMENT
For: CIRCULATING MRNA AS DIAGNOSTIC MARKERS	
Customer No.: 45115	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the restriction requirement mailed March 22, 2006, Applicants elect Group I, claims 1-11, drawn to methods for diagnosing pre-eclampsia. With regard to the genes recited in the Markush group, Applicants elect the gene of human corticotrophin releasing hormone (hCRH). This election is made with traverse.

Filed concurrently is a petition to extend time to respond for two months, from April 22, 2006, to June 22, 2006.

Basis for restriction practice is illustrated in 35 U.S.C. §121, "[i]f two or more independent and distinct inventions are claimed in one application, the Director [of the Patent and Trademark Office] may require the application to be restricted to one of the inventions." According to MPEP §803, there are two requirements that must be met before a proper restriction requirement can be imposed: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that it has not been established that the second requirement under MPEP §803 is met, in other words, a serious burden exists on the Examiner if restriction is not required among the groups of claims.

The present application relates to diagnostic methods for various conditions based on the quantitative detection of circulating mRNA of certain genes including hCG-β, hPL, hCRH, KISS-1, TPGI2, PLAC1, and GAPDH. Groups I, III, V, VI, and VIII contain method claims reciting the same steps of quantitative detection of mRNA of the same group of genes, whereas Groups II, IV, VII, and IX contain kit claims corresponding to the method claims. Because the subject matter of the restriction requirement is so closely related, a search and examination of the claims of Group I would largely overlap the search and examination for the remaining Groups, particularly Groups III, V, VI, and VIII. Any additional search would be minimal and constitute no serious burden on the Examiner. As such, Applicants respectfully request that the Examiner to reconsider and withdraw the restriction requirement.

Concerning the required election for one of the genes recited in the Markush group, Applicants contends that the requirement is highly improper and strongly traverse the requirement. First of all, MPEP §803.04 provides a special rule on restriction practice involving nucleotide sequences. This section explicitly states that, despite the independent and distinct nature of multiple nucleotide sequences, the Commissioner has partially waived the requirements of 37 C.F.R. §1.141 and permits a reasonable number of such nucleotide sequences to be claimed in a single application to "further aid the biotechnology industry in protecting its intellectual property." This section also states that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purpose. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without

restriction." In accordance with this section, Applicants respectfully request that the Examiner examine the claims with regard to all seven gene recited in the Markush group.

Secondly, the required election of only one gene among the seven recited in the Markush group places on Applicants a financial burden so tremendous that it eliminates any realistic possibility for Applicants to pursue the full scope of patent protection they rightfully deserve. The Examiner first divides the pending claims into nine groups and requested restriction to one; the Examiner then requests the election of one gene out of the seven genes named in the claims for each group. If this restriction requirement is maintained, Applicants will have to file a total of 63 patent applications! This is an unfair burden no patent applicant should or could carry, especially compared to the minor burden on the Examiner if all genes are examined together. This is also precisely the type of situation MPEP §803.04 is intended to prevent. Applicants thus strongly urge the Examiner to reconsider and withdraw the requirement for restricting the invention to one gene only.

If, on the other hand, the Examiner's requirement for the election of a gene among those recited in the Markush group is one for a provisional election under MPEP §803.02, Applicants then fully expect the Examiner to extend the search for the Markush-type claim to the non-elected species, once the elected species is deemed free of art.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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